EXHIBIT “D”

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Ice cream / Labeling - / Vanilla Flavoring

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Re: Labeling of Ice Cream Products Flavored with Vanilla Docket No. 80A-0209

Dear Sirs:

On May 16, 1980, the Flavor and Extract Manufacturers' Association (FEMA) filed a request for an advisory opinion regarding the labeling of ice cream products flavored with vanilla. FEMA presented a letter from a Bureau of Foods employee (the Newberry letter) and requested that the agency confer advisory opinion status on the letter's interpretation of the labeling requirements in the ice cream regulation (21 CFR 135.110). I signed an advisory opinion granting this request on February 12, 1981.

The ice cream regulation establishes a three-tiered system of labeling that is based on the amount of the natural characterizing flavor a product contains, and on whether, if the product contains both a natural characterizing flavor and an artificial flavor that simulates it, the natural characterizing flavor predominates. Under this system, natural vanilla flavor predominates, and ice cream can be labeled as "vanilla flavored," when the product contains one ounce of vanillin per unit of vanilla constituent. The advisory opinion sets forth FDA's view that when any flavor from a non-vanilla bean source that simulates vanilla is added to such a product, the natural flavor no longer predominates, and the product can no longer be labeled "vanilla flavored."

On February 23, 1981, David Michael & Co. (the objector) wrote to Secretary Schweiker and objected to this advisory opinion. On February 27, 1981, the agency stayed the opinion

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to consider the objection and to provide the objector with an opportunity to submit additional material.

I have now fully considered the issues raised by the advisory opinion and by the objection. I have carefully reviewed the extensive memoranda submitted by both the objector and FEMA, the attachments to these memoranda, and the written comments of the International Association of Ice Cream Manufacturers (IAICM). I have also met with representatives of the objector, IAICM, and FEMA.

As a result of my deliberations, for the reasons discussed below, I have decided to reaffirm the February 12, 1981 advisory opinion.

I. The Advisory Opinion Is An Interpretative Rule And Therefore Not Subject to Section 701(e) of the Food, Drug, And Cosmetic Act or to the Administrative Procedure Act

The objector contends that the advisory opinion effectively amends 21 CFR 135.110(e)(2)(ii) to prohibit the use of non-characterizing natural ingredients in "vanilla flavored" ice cream. Objector's April 6, 1981 submission, p. 35. The objector argues that the opinion thus was improperly issued because a standard of identity established under section 401 of the Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 341, can only be amended after compliance with section 701(e) of that statute, 21 U.S.C. 371(e).

The objector is incorrect for two reasons. First, as will be discussed in more detail below, the advisory opinion deals only with the effect on ice cream labeling of the use of flavoring ingredients that simulate the characterizing flavor. It has no bearing on the labeling of ice cream that contains flavors that do not simulate the characterizing flavor.

Second, and more importantly, under the test established in Gibson Wine Co. v. Snyder, 194 F.2d 329 (D.C. Cir. 1952), the advisory opinion is an interpretative rule. In Gibson Wine Co., supra, 194 F.2d at 331, the court stated:

> Generally speaking, it seems to be established that "regulations," "substantive rules" or "legislative rules" are those which create law, usually implementary to an existing law; whereas interpretative rules are statements as to what

the administrative officer thinks the statute or regulation means.

See also Cabais v. Egger, 690 F.2d 234, 238 (D.C. Cir. 1982). The February 12, 1981 advisory opinion presents the agency's view on how 21 CFR 135.110(e)(5)(i) requires a manufacturer to label a product that contains flavor consisting of one ounce of vanillin per unit of vanilla constitutent plus any amount of a flavor from a non-vanilla source that simulates vanilla. It does not make any change in 21 CFR 135.110(e)(5)(i).

In the preamble to FDA's proposed procedural regulations (40 FR 40682 (September 3, 1975)), the agency anticipated the situation presented here and specifically stated that whether the labeling of a product is consistent with the agency's regulations would be an appropriate subject for an advisory opinion. 40 FR 40695. Thus, the February 21, 1981 advisory opinion is an interpretative rule and is not subject to the provisions of 21 U.S.C. 371(e). (As an interpretative rule, the advisory opinion is also exempt from the provisions of the Administrative Procedure Act (APA). 5 U.S.C. 553(b)(B).)

The cases cited by the objector in its April 16, 1981 submission (pp. 29-34) are not to the contrary. Both Guardian Federal Savings & Loan v. Federal Savings & Loan Insurance Corp., 589 F.2d 658, 644 (D.C. Cir. 1978) and Chamber of Commerce of United States v. OSHA, 636 F.2d 464, 469 (D.C. Cir. 1980) utilize the test enunciated in Gibson Wine Co. v. Snyder, supra. Noel v. Chapman, 508 F.2d 1023 (2d Cir.), cert. denied 425 U.S. 824 (1975) and Parco v. Norris, 426 F.Supp. 976 (E.D. Pa. 1977) are not relevant. They relate to the distinction between general statements of policy and substantive rules and not to the distinction between interpretative and substantive rules. Finally, even if an agency action has substantial impact, it is still not subject to notice and comment rulemaking if, like the February 12, 1981 advisory opinion, it is otherwise expressly exempt under the APA. Cabais v. Egger, supra, 690 F.2d at 237.

Therefore, the February 12, 1981 opinion is not a substantive regulation and can properly be issued as an advisory opinion by FDA.

II. The Advisory Opinion Was Issued In Accordance With Appropriate Procedures

The objector has charged that even if the February 12, 1981 advisory opinion is an advisory opinion, it was issued in contravention of FDA's procedures on advisory opinions, the President's moratorium on regulations, and Executive Order 12291. Again, I find that I do not agree with the objector.

Section 10.85(a)(1) of FDA's regulations (21 CFR 10.85(a)(1)) enunciates the agency's policy of granting a request for an advisory opinion whenever feasible. In 1981, the agency found that it could issue an advisory opinion in response to FEMA's request. I find no basis upon which to conclude that this decision was inconsistent with 21 CFR 10.85.

Because the request for the advisory opinion seeks the agency's interpretation of an FDA regulation, the request presents a policy issue of broad application and not one applicable only to a particular product. Because FDA has long experience in administering the ice cream standard of identity, even though this matter is complex (see page 41 of the objector's April 6, 1981 submission), the agency had adequate information upon which to issue an informed advisory opinion in 1981. In addition, now that the agency has had the benefit of the comments of the objector, FEMA, and IAICM, there can be no question about the adequacy of the information underlying my decision to reinstate the advisory opinion. Finally, because there apparently is some confusion about the agency's interpretation of 21 CFR 135.110, it is in the public interest to issue this advisory opinion. Therefore, I find no basis in 21 CFR 10.85 for not reinstating the February 12, 1981 advisory opinion.

However, I agree with the objector that FEMA's request for an advisory opinion was not adequate under 21 CFR 10.85(b). A person who requests an advisory opinion from FDA has an obligation to provide a full statement of all facts and legal points relevant to the request. The requestor is not free, as FEMA did, to make assumptions about what information is or is not known to the agency. In addition, FEMA inaccurately described the Newberry letter in its request. The request states that the Newberry letter "...answers the question: What is the legal name of an ice cream product, the flavor of which 'consisted of one ounce of vanillin per unit of vanilla constituent and any flavor from a non-vanilla bean source....'" "Request for an Advisory

Opinion," dated May 16, 1980, from John G. Adams, past President of FEMA, p. 1. In fact, the Newberry letter was qualified and dealt only with those flavors from non-vanilla bean sources that "simulate, resemble, or reinforce" the vanilla flavor. FEMA's inaccurate description of the Newberry letter undoubtedly contributed to the confusion surrounding this proceeding.

In many cases, FDA would consider denying, under 21 CFR 10.85(a)(2)(i), a request like that submitted by FEMA because it presents insufficient information. The agency has committed itself to granting an advisory opinion when feasible (21 CFR 10.85(a)(1)); however, and in the circumstances presented here, for the reasons I have discussed, it is feasible to respond to FEMA's request.

The advisory opinion did not violate the President's moratorium or Executive Order 12291. Both of these directives applied only to regulations required to be promulgated by informal notice and comment rulemaking under the APA. As I explained previously, this advisory opinion is not the subject of notice and comment rulemaking. In fact, on February 10, 1981, Secretary Schweiker issued a memorandum to officials in the Department of Health and Human Services in which he stated that the President's directive does not apply to policy-setting actions outside the scope of the APA's informal rulemaking process. Among the examples he gave were interpretative rulings. As stated above, FDA's advisory opinions are interpretative rulings.

The objector also contends that FDA should have complied with the Regulatory Flexibility Act (RFA) in issuing the advisory opinion. By its terms, the RFA applies only to rules issued by notice and comment rulemaking, and, thus, this statute too does not apply to the advisory opinion.

III. The Advisory Opinion Is Correct And Is Consistent With Longstanding FDA Policy

After carefully considering all the information submitted on the appropriateness of the February 12, 1981 advisory opinion, I have concluded that that opinion is correct, and that it is consistent with the prior statements made by FDA. Therefore, I am reinstating this advisory opinion. However, before explaining the basis on which I reached these conclusions, I will address a preliminary matter that was debated in the comments on the advisory opinion. My determination on this preliminary matter establishes the foundation on which my other conclusions rest.

A. The Relationship Between §§135.110 and 101.22

The objection and the other comments FDA received on the advisory opinion contained a significant amount of discussion on the relationship between the ice cream regulation (21 CFR 135.110) and the general flavoring regulations (21 CFR 101.22). For example, the objector accused the agency of selectively borrowing from the general flavoring regulations in reaching its advisory opinion. See, e.g., Objector's April 3, 1981 submission, p. 41. After carefully considering this issue, I agree with the statement made by Taylor Quinn, Associate Director for Compliance of the Bureau of Foods, in his letter of May 31, 1979, to Glenn P. Witte of IAICM: "The general flavor regulations are not applicable to this standardized food [ice cream]."

The regulatory scheme under the general flavor declaration requirements of 21 CFR 101.22 is significantly different from the three-category labeling scheme in the ice cream regulation for declaring the characterizing flavor in ice cream. For example, under the general flavor regulations, if a food contains any artificial flavor that simulates, resembles, or reinforces the characterizing flavor, the food must be labeled "artificially flavored." 21 CFR 101.22(i)(2). In contrast, under the ice cream regulation, if the food contains both a natural characterizing flavor and an artifical flavor simulating it, the food need not be labeled as artifical unless the artificial flavor predominates (although when the natural flavor predominates, the presence of the artifical flavor must be indicated on the label). 21 CFR 135.110(e)(2)(ii). At the time FDA adopted the general flavor regulations, the agency considered revising the ice cream regulation to make it consistent with the general flavoring regulations. 38 FR 33284, 33287 (December 3, 1973). See also 39 FR 27144, 27145 (July 25, 1975). However, the agency ultimately decided to retain the three-category labeling scheme in the ice cream regulation. 42 FR 19127, 19131 (April 12, 1977). Because of the differences between the two regulations, the general flavoring regulations have no relevance to this matter.

However, the fact that the general flavoring regulations themselves are not relevant does not mean that all of the information contained in preambles to Federal Register notices on those regulations is also irrelevant. Not only is a preamble to a regulation an advisory opinion, 21 CFR 10.85(d)(1), but there is also a significant agency interest in being consistent among its regulations, at least in such matters as terminology. Therefore, a discussion in the pre-

amble to the general flavoring regulations about the meaning of a term that is used in the ice cream regulation as well as in the general flavoring regulations is applicable to both regulations.

One example of such a discussion is comment 17 to the December 3, 1973 final rule on the general flavor regulations. The paragraph explaining the subject of that comment states:

> 17. Questions have arisen as to how the characterizing flavor is to be determined, and as to how it will be determined whether added flavor "simulates" a characterizing natural flavor or otherwise characterizes the product.

Because the ice cream regulation also uses both "characterizing flavor" and "simulating," the discussion in comment 17 would obviously be relevant in interpreting the ice cream regulation as well as the general flavoring regulation.

On the other hand, because of the differences between the ice cream regulation and the general flavoring regulations, some agency discussions of one of these regulations will not be applicable to the other. For example, the Newberry letter concerns a product that contains a flavor consisting of one ounce of vanillin per unit of vanilla plus an additional amount of flavor from a non-vanilla bean source that simulates vanilla. Although such a product would be labeled as "artifically flavored" under both the general flavoring regulations and the ice cream regulations, the reasons for doing so would be completely different under §101.22 (the product contains artifical flavor, vanillin) than under §135.110 (the natural characterizing flavor does not predominate under the facts specified). Because the Newberry letter concerns only the application of the ice cream regulation, contrary to the claims of the objector (see Objector's submission of August 31, 1981, p. 8), it would not be relevant in interpreting 21 CFR 101.22.

B. The Advisory Opinion Correctly Interprets 21 CFR 135.110

Perhaps the best way to analyze the February 12, 1981 advisory opinion is to look at the portion of the Newberry letter that is quoted in the opinion on a sentence-by-sentence basis. There is no controversy about the first sentence, which merely restates the contents of 21 CFR 135.110(e)(5)(i), or about the last sentence, which simply follows from the two that precede it. The real concern is

over the middle two sentences. Thus, a closer analysis of these statements in the advisory opinion is necessary.

1. "Consequently, an ice cream manufacturer could not call his product 'vanilla flavored ice cream' (Category II) if the flavor consisted of one ounce of vanillin per unit of vanilla constituent and any flavor from a non-vanilla bean source (which simulated, resembles, or reinforces the vanilla flavor) is added to the product."

This sentence states that if any amount of flavor that simulates vanilla, the natural characterizing flavor, is added to the balance of vanilla and vanillin at which the vanilla is deemed to predominate, natural vanilla will no longer predominate. This statement is consistent with both 21 CFR 135.110 and the prior statements of the agency.

a. The use of the words "simulates, resembles, or reinforces" in this sentence, rather than the word "simulates" alone, is consistent with the agency's longstanding interpretation of the latter term. As explained above, it is appropriate to use the December 3, 1973 preamble in interpreting the ice cream regulation. In that preamble, in response to questions about how to determine "whether added flavor 'simulates' a characterizing natural flavor," the agency states that the test is not solely whether the flavor simulates or is chemically identical to the characterizing flavor, but also whether it resembles, reinforces, or extends it. 38 FR 33286. Thus, it was appropriate to incorporate "resembles" and "reinforces" into this sentence of the advisory opinion.

b. It is clear from the context in which the Newberry letter was written that the subject of the letter was a flavor that simulates the characterizing flavor. The Newberry letter was written after a meeting between Anthony Filandro of Virginia Dare Extract Co. and Daniel R. Thompson, counsel to FEMA, and Taylor Quinn, James Summers, and R. E. Newberry of FDA. The memorandum of this meeting indicates that Messers Filandro and Thompson inquired about the effect of "adding a natural flavor from a non-vanilla bean source which simulates, resembles, and reinforces the vanilla flavor." The Newberry letter, by its own terms, was intended to respond to this inquiry. Thus, the Newberry letter was not intended to set forth the effect of adding a non-characterizing flavor to a mixture of vanillin and vanilla constituent.

c. The Newberry letter is correct under 21 CFR 135.110(e). Because that section makes no provision for any natural flavors other than natural characterizing flavors, FDA must treat all natural flavors that simulate the characterizing flavor as artifical flavors when deciding what name should appear on the principal display panel. Thus, the addition of a flavor that simulates vanilla to ice cream that contains one ounce of vanillin per unit of vanilla constituent would mean that the balance at which the natural characterizing flavor -- vanilla -- predominates would no longer obtain. In such circumstances, the artificial flavor -- including natural flavors simulating vanilla -- will be deemed to predominate.

d. This sentence of the advisory opinion is consistent with prior statements made by the agency. On May 31, 1979, in response to a letter from Glenn P. Witte of the IAICM, Mr. Quinn wrote:

> It is our understanding that there are available in the market place, natural flavoring compounds that resemble, simulate and/or enhance vanilla flavor but are not derived from vanilla bean. These flavor compounds would not comply with the intent of the flavor provisons of Category I ice cream. However, they would qualify for category II labeling (vanilla flavored ice cream) provided that the flavor derived from vanilla beans predominates.

See also Letter of August 22, 1979, from Mr. Quinn to Kenneth B. Basa, National Food Ingredients Company, which contains a statement to the same effect.

Both the advisory opinion and the Quinn letter to Witte reflect the fact that FDA will treat natural flavor compounds that simulate vanilla but are not derived from vanilla beans as artificial flavors that simulate the natural characterizing flavor. The Quinn letter states that these natural flavor compounds can be used with natural vanilla flavors to make "vanilla flavored" ice cream, so long as the natural vanilla flavor predominates. The advisory opinion does not say that these compounds cannot be used to make such a product. What the advisory opinion does say is that if a natural flavor compound that simulates vanilla is added to vanilla flavored ice cream that is formulated at the point of predominance of the natural characterizing flavor (one ounce of vanillin per unit of vanilla constituent), the addition of this compound will mean that the natural characterizing

flavor no longer predominates. There is nothing in the Quinn letter to the contrary.

2. "The non-vanilla flavor is deemed to simulate vanilla if the addition of the non-vanilla flavor results in a reduction in the amount of vanilla bean derived flavor that would otherwise be used in a vanilla flavored ice cream."

a. The objector claims that the test embodied in this sentence establishes a minimum amount of natural vanilla flavored ice cream, and that the sentence consequently is inconsistent with 21 CFR 135.110. Objector's submission of August 31, 1981, p. 51. The objector misapprehends the meaning of this sentence. The sentence is not about how much vanilla must be in a product to call it "vanilla flavored" but about how to determine whether a flavor simulates the characterizing flavor. The agency first established this test in its response to comment 17 in the December 3, 1973 preamble. There FDA said that a flavor that extends the characterizing flavor, that is, makes it appear that more of the characterizing flavor is present than is actually the case, simulates the characterizing flavor. 38 FR 33286. Thus, a flavor that permits less of the characterizing flavor to be used than would otherwise be the case simulates that flavor.

The objector argues that comment 17 establishes taste as the only test for determining whether an added flavor simulates a characterizing natural flavor. Objector's submission of April 6, 1981, p. 54. In support of this contention, the objector cites the following language from comment 17:

> ...In determining whether added flavor does or does not simulate, resemble, or reinforce the characterizing flavor, the principal test will be to separate such added flavor from the product to determine whether it tastes like the characterizing natural flavor or approximates the flavor characteristics of any principal or key flavor note....

Id. In so arguing, however, the objector ignores the fact that the portion of comment 17 that he quotes speaks of the "principal test." Implicit in the use of these words is the fact that there are other criteria besides taste that are to be applied in deciding whether a flavor simulates the characterizing flavor. One of those tests is whether the flavor

extends the characterizing natural flavor. Thus, under comment 17, if an ice cream manufacturer added a small amount of a natural flavor not derived from the vanilla bean to his mix to permit the use of a smaller amount of vanilla-vanillin flavor, the natural flavor would simulate the characterizing flavor.

Therefore, the objector's claim that this sentence of the advisory opinion is inconsistent with 21 CFR 135.110 and with comment 17 in the December 3, 1973 preamble is without merit.

b. The objector contends that the test established in this sentence of the advisory opinion for determining whether a non-vanilla flavor simulates vanilla violates the principles established in United States v. 88 Cases, ... Birely's Orange Beverage, 187 F.2d 967 (3d Cir.), cert. denied 342 U.S. 861 (1951). Objector's February 23, 1981 submission, p. 8 and Objector's August 31, 1981 submission, p. 48. FDA finds this claim to be groundless.

The Birely's case turned on the question of whether there was any danger of confusing the product at issue with something else that is defined, familiar, and superior. 187 F.2d at 972. In Birely's, the court found that such a danger did not exist because there was no standard for diluted orange drinks like that made by the claimant, and because there was no danger that an ordinary consumer would confuse the claimant's product with undiluted orange juice. Id. at 973. Here, however, there is such a danger. Contrary to the claims of the objector (see Objector's submission of August 31, 1981, p. 51), FDA has established a standard for what can be called "vanilla flavored ice cream." The advisory opinion is intended to prevent consumer confusion by preventing the application of this name to products that do not meet the standard. Thus, the situation here is clearly distinguishable from that in the Birely's case.

For this reason, and because, as FEMA has pointed out, FEMA's submission of June 29, 1981, p. 18, this case involved application of section 401 of the FD&C Act, while Birely's involves application of section 402, and the two sections

have no relation to one another,*/ the principles enunciated in Birely's are not applicable to the immediate case

C. The Consumer Preference For Natural Flavors Is Irrelevant To This Matter.

The objector contends that the February 12, 1981 advisory opinion ignores the demonstrated consumer preference for natural products and for products that contain natural additives. Objector's April 6, 1981 Submission, p. 50. This contention may well be true, but it is irrelevant to a decision in this matter.

For ice cream, the name that appears on the principal display panel is determined by the factors set forth in 21 CFR 135.110(e). Under the labeling scheme established in that provision, whether a flavor is natural is significant only when that flavor is the characterizing flavor, in this case, vanilla. Any flavor, whether natural or not, that is used in ice cream to simulate the characterizing vanilla flavor is treated as an artificial flavor, unless it is derived from vanilla beans. If the objector wishes to change this scheme to reflect the claimed consumer interest in natural flavors, it is free to petition the agency to amend the regulation. For now, however, the advisory opinion must, as it does, reflect the regulation that is currently in effect.

IV. Conclusion

For the foregoing reasons, I find that the February 12, 1981 advisory opinion is consistent with 21 CFR 135.110 and with the prior statements made by FDA. Therefore, I am lifting the stay on the advisory opinion and reinstating this advisory opinion.

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*/ "...[S]ection [401]...has no relation to, no connection with, the adulteration provisions of the Act." Bruce's Juices v. United States, 194 F2d 935, 936 (5th Cir. 1952), citing United States v. 36 Drums of Pop'n Oil, 164 F.2d 150 (5th Cir. 1947).

On behalf of FDA, I would like to thank those who submitted comments and who met with me for their interest and contribution to the decisionmaking process in this matter.

Sincerely,

Joseph P. Hile

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Associate Commissioner for
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